## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

IN RE BENDAMUSTINE CONSOLIDATED CASES

C.A. No. 13-2046-GMS (consolidated)

DEFENDANTS SAGENT, DRL, PHARMASCIENCE AND INNOPHARMA'S REPLY BRIEF IN SUPPORT OF THEIR RULE 12(C) MOTION FOR JUDGMENT ON THE PLEADINGS

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# I. Defendants' motion is a timely and properly-filed motion for judgment on the pleadings under Fed. R. Civ. P. 12(c).

Because defendants cite excerpts from their respective ANDAs, Cephalon argues that defendants' motion for judgment on the pleadings must be converted to a summary-judgment motion, and as a summary-judgment motion, violates the Court's scheduling order. D.I. 108 at 4-5. Cephalon is incorrect.

It is well-established law that a "document integral to or explicitly relied upon in the complaint" may be considered "without converting [a] motion to dismiss into one for summary judgment." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis in original). Cephalon acknowledges this law in its answering brief, but omits the latter quote in Burlington that in such circumstances a motion to dismiss is not converted to one for summary judgment. D.I. 108 at 4. That defendants rely on their ANDAs to support their motion is no surprise to Cephalon. Those ANDA documents are "integral to" and "explicitly relied upon" in Cephalon's Complaints. Burlington, 114 F.3d at 1426 ("[B]y looking to documents outside the complaint—lack of notice to the plaintiff—is dissipated '[w]here plaintiff has actual notice . . . and has relied upon these documents in framing the complaint.'"). Cephalon acknowledges reviewing defendants' ANDA documents before filing suit and admits this in its brief. D.I. 58 at 3-4; D.I. 108 at 2.

Indeed, in a Hatch-Waxman case, the Federal Circuit found *no* error in granting defendants' motions to dismiss where the Delaware district court considered certain documents beyond the pleadings, including defendants' ANDA filings, Section viii statements, and proposed product labeling. *Astra Zeneca Pharmaceuticals LP v. Apotex* 

Corp., 669 F.3d 1370, 1378 n.5 (Fed. Cir. 2012); see also Bayer Schera Pharma AG v. Sandoz, Inc., 741 F. Supp. 2d 541, 544-45 n.4 (S.D.N.Y. 2010) (granting a Rule 12(c) motion based on defendants' ANDA documents, and holding that consideration of those ANDA documents do not convert defendants' motion to one for summary judgment).

Courts can also "look to the prosecution history for purposes of [a] Rule 12(c)" motion. *buySAFE, Inc. v. Google, Inc.*, 964 F. Supp. 2d 331, 335 (D. Del. 2013), aff'd, 765 F.3d 1350 (Fed. Cir. 2014); *Desemberg v. Google, Inc.*, 392 F. App'x 868, 872 (Fed. Cir. 2010) (relying on the file history of the patent-at-issue in deciding a Rule 12(b)(6) motion).

This motion is not converted to a summary-judgment motion because defendants rely on portions of their ANDAs and the prosecution histories of the '190 and '863 patents. Pursuant to Rule 12(c), defendants have timely moved for judgment on the pleadings after those pleadings were closed, but early enough not to delay trial. Fed. R. Civ. P. 12(c); see also The Money Suite Co. v. 21st Century Insur. and Financial Srvcs Inc., et. al., Case No. 13-1748-GMS (D. Del. Jan. 27, 2015) (attached as Ex. A) (granting rule 12(c)/12(b)(6) motions because patents were invalid). This Court may properly consider defendants' ANDA documents and the patent prosecution histories to hold, as a matter of law, that the disclosure-dedication rule bars Cephalon's infringement claims under the doctrine of equivalents.

II. Defendants' motion for judgment on the pleadings does *not* raise disputed facts for the Court to resolve; the sole issue here is a question of law.

Cephalon argues that it pled sufficient facts to place defendants on notice of its infringement allegations, that those facts must be accepted as true and construed in Cephalon's favor. (D.I. 108 at 6-8). But that is *not* the issue before the Court; defendants

are not challenging the sufficiency of Cephalon's notice pleading. And though it is well-established law that factual allegations must be accepted as true, it is equally well-established that a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain,* 478 U.S. 265, 286 (1986); *Baraka v. McGreevey,* 481 F.3d 187, 195 (3d Cir. 2007) (same).

This is all that Cephalon has done here. Though Cephalon alleges ownership of the '190 and '863 patents and states that defendants filed ANDAs seeking approval to sell generic bendamustine products (*see e.g.* Cephalon's Complaint against Sagent (D.I. 1 at ¶¶ 16-25)), Cephalon offers a bare legal conclusion when it alleges that defendants' "use of a lyophilized bendamustine hydrochloride pharmaceutical composition in the manufacture of Defendants' Bendamustine Product infringes one or more claims" of the '190 and '863 patents. *Id.* at ¶¶ 75 and 98. Cephalon cannot defeat defendants' Rule 12(c) motion based on legal conclusions in its Complaints.

Cephalon also says, "[a]t the very least," the equivalence between tertiary-butyl alcohol and defendants' solvents "is a question of fact that must be determined after the completion of fact and expert discovery." D.I. 108 at 8. But like Cephalon's notice-pleading argument, the factual equivalence of defendants' solvents is a false issue that Cephalon raises to divert the Court's attention from what this motion is all about. There are no factual issues for the Court to resolve. Instead, the sole issue here is a question of law: whether the disclosure-dedication rule bars Cephalon's claims for infringement under the doctrine of equivalents.

III. The disclosure-dedication rule bars Cephalon's claims for infringement under the doctrine of equivalents because the '190 and '863 patents specifically disclose but do not claim the solvents used in defendants' ANDA products.

After spending the bulk of its time arguing that defendants' motion should be denied on procedural grounds, Cephalon gets to the merits of the disclosure-dedication rule at the last three pages of its answering brief. D.I. 108 at 9-12.

As defendants explained previously, the '190 and '863 patent specifications disclose specific alternative solvents to tertiary-butyl alcohol. D.I. 58 at 5-6. Cephalon does *not* dispute that those disclosures are sufficiently specific for a person of ordinary skill in the art to identify what has not been claimed. *See* D.I. 108 at 9-12; *PSC Computer Products, Inc. v. Foxconn Int'l, Inc.,* 355 F.3d 1353, 1360 (Fed. Cir. 2004) ("The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.").

Faced with the explicit disclosures in the patent specifications and the undisputed fact that the *only* solvent recited in the '190 and '863 patent claims is tertiary-butyl alcohol, Cephalon attempts to escape the disclosure-dedication rule by arguing that "*Johnson & Johnston* does not govern this case." D.I. 108 at 9. Cephalon argues that *Johnson & Johnston* made clear that a dedication does not occur where "the patentee originally sought to claim or did in fact claim the subject matter elsewhere." *Id.* Cephalon says that it is "[l]ike the patentee in *Graver Tank*," and notes that it sought claims to the alternative solvents in its original '190 patent application. *Id.* at 9-10.

Cephalon also notes that it actually obtained claims to those alternative solvents in its related '350 patent. *Id.* at 10. "In contrast," Cephalon says that "the patentee in *Johnson* 

& Johnston never sought claims covering the alleged equivalent in that case." *Id.*Accordingly, because Cephalon sought claims reciting the alternative solvents in its original application and ultimately obtained claims for those solvents in a later-issued '350 continuation patent, Cephalon argues that the disclosure-dedication rule does not apply.

Cephalon's arguments fail on several grounds. *First*, Cephalon is inaccurate when it argues that it is "[l]ike the patentee in *Graver Tank*." D.I. 108 at 9-10. As the Federal Circuit explained in *Johnson v. Johnston*, in *Graver I*, the Supreme Court held invalid the two composition claims directed to "silicates" and "metallic silicates" because those claims were too broad and included inoperative embodiments. *Johnson & Johnston Associates v. R.E. Service Co., Inc., et al.*, 285 F.3d 1046, 1053 (Fed. Cir. 2002) (citing Graver Tank & Mfg. Co. v. Linde Air Products Co., 336 U.S. 271(1949)). The Supreme Court, however, did not hold invalid the narrower claims comprising "alkaline earth metals." *Id.* In the subsequent infringement action of *Graver II*, the Court found that the accused compositions, which comprised a metallic silicate, infringed the surviving narrower claims under the doctrine of equivalents. *Id.* (citing Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605 (1950)).

That is not the situation here. Unlike *Graver Tank* where issued claims 24 and 26 recited "silicates" and "metallic silicates," the '190 and '863 patents never issued with claims broadly reciting the genus of "solvents" or any of the specific alternative solvents in the specification. As issued, the '190 and '863 patents only claim tertiary-butyl alcohol.

Second, Cephalon's argument is the direct opposite of what Johnson & Johnston held. As mentioned above, the Federal Circuit distinguished Graver Tank on the grounds that the patent-in-suit had issued with claims to the equivalent silicates. But further, in Johnson & Johnston the Federal Circuit held that the disclosure-dedication rule barred the patentee's claim for infringement under the doctrine of equivalents even though the patentee had filed continuation applications for the dedicated subject matter. Specifically, the Federal Circuit held that,

A patentee who inadvertently fails to claim disclosed subject matter, however, is not left without remedy. Within two years from the grant of the original patent, a patentee may file a reissue application and attempt to enlarge the scope of the original claims to include the disclosed but previously unclaimed subject matter. 35 U.S.C. § 251 (2000). In addition, a patentee can file a separate application claiming the disclosed subject matter under 35 U.S.C. § 120 (2000). Notably, Johnston took advantage of the latter of the two options by filing two continuation applications that literally claim the relevant subject matter.

Johnson & Johnston, 285 F.3d at 1055.

Thus, contrary to Cephalon's assertion, in *Johnson & Johnston* the patentee sought claims covering the alleged equivalent in continuation applications, but the disclosure-dedication rule nonetheless *applied to the patent-in-suit*. As the Federal Circuit explained, allowing a patentee to recapture disclosed but unclaimed subject matter "conflict[s] with the primacy of the claims in defining the scope of the patentee's exclusive right." *Id.* at 1054 (internal citations omitted). The law provides that each patent has its own metes and bounds, and is a separate chose in action. *Comair Rotron, Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1539 (Fed. Cir. 1995); *Stark v. Advanced Magnetics, Inc.*, 29 F.3d 1570, 1576 (Fed. Cir. 1994). This is consistent with the Supreme Court precedent the

Federal Circuit looked to in *Johnson & Johnston. See* 285 F.3d at 1052-53 (quoting *Mahn v. Harwood,* 112 U.S. 354, 360-61 (1884); *Miller v. Bridgeport Brass Co.,* 104 U.S. 350, 352 (1881)). That unclaimed subject matter has been claimed in a related continuation patent has no bearing on whether there has been a disclaimer of that unclaimed subject matter *in the patent-in-suit.* Here, the '190 and '863 patent specifications disclose alternative solvents, but do not claim them. Under *Johnson & Johnston* the disclosure-dedication rule applies to those patents, full stop. Cephalon's remedy for not claiming them is the '350 patent.

Citing Johnson & Johnston, Cephalon also argues that the disclosure-dedication rule does not apply because it "tried to claim" the alternative solvents in the '190 patent application, and therefore, did not "decline" to claim them. D.I. 108 at 11. This argument also fails. In support, Cephalon cites to *Graver Tank*, once again, and the district court decisions in *Janssen* and *Rosby*. But as explained above, *Graver Tank* is distinguishable because the patentee did in fact obtain issued claims reciting the equivalent metallic silicate *in the patent-in-suit*. *Johnson & Johnston*, 285 F.3d at 1053. Cephalon never obtained claims to the alternative solvents *in the patents-in-suit*, i.e., the '190 and '863 patents.

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<sup>&</sup>lt;sup>1</sup> When Cephalon states that it "tried to claim" the alternative solvents in its original '190 patent application, it fails to mention what happened to those claims during prosecution. As filed, claims 20 and 21 recited various solvents in addition to tertiary-butyl alcohol. After receiving an obviousness rejection, Cephalon *amended* its original claims *by canceling* claims 20 and 21, and proceeding with claims reciting only tertiary-butyl alcohol. *See* Ex. B at CEPH\_00002228-32 and CEPH\_00002339-43.

As to the '863 patent, Cephalon fails to mention that it never submitted any claims to the alternative solvents during prosecution. From the beginning, the claims in the '863 patent application recited only tertiary-butyl alcohol. *See* Ex C at CEPH\_00003441.

Cephalon is also wrong on the law. It does not matter if Cephalon tried to claim the dedicated solvents in its original application for the '190 patent. The Federal Circuit refuted Cephalon's argument that disclosure-dedication only occurs when the patentee affirmatively "declines to claim [that] subject matter." *Id.* at 1053 n.1. Indeed, to the extent there was any ambiguity in *Johnson & Johnston* over the clause "declines to claim [that] subject matter," the Federal Circuit addressed it head-on in *Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1332-33 (Fed. Cir. 2004). In *Toro*, the patentee argued that its failure to claim the equivalent structure was "wholly unintentional," and that it actually claimed that structure in the patent-in-suit because it used the word "including" in its claims. *Id.* at 1332. The Federal Circuit rejected *Toro's* argument:

We hold, as a matter of law, that intent is not part of the *Johnson & Johnston* disclosure-dedication analysis . . . . Because intent is not a factor in applying the disclosure-dedication rule, Toro cannot prevail as a matter of law based on its argument that it did not decline to claim or deliberately leave unclaimed the structure of White's device.

383 F.3d at 1333. Significantly, the Federal Circuit also rejected *Toro's* argument that it was like the patentee in *Graver Tank*, an argument Cephalon makes here. "In *Graver Tank*, there was no question that the applicant actually claimed the subject matter at issue even though the claims were later invalidated." *Id*.

Cephalon's reliance on *Janssen* and *Rosby* — two non-controlling district court cases — is also misplaced.<sup>2</sup> In a common refrain, the patentees in those two cases argued that they were "like *Graver Tank*" because unissued claims in their original patent

<sup>&</sup>lt;sup>2</sup> Cephalon's affiliate, Teva Pharmaceuticals USA, is a defendant in the *Janssen* case and is arguing on appeal that the disclosure-dedication doctrine bars, as a matter of law, the patentee's claim for infringement under the doctrine of equivalents.

applications showed they "tried to claim" and did not "deliberately leave unclaimed" the subject matter, so the disclosure-dedication rule did not apply. See Janssen Products, L.P. v. Lupin Ltd., No. 2:10-cv-05954-CLW, 2014 U.S. Dist. LEXIS 155248 at \*75 (D.N.J. Mar. 12, 2014); Rosby Corp. v. Stoughton Trailers, Inc., No. 95 C 511, 2003 WL 22232802 at \*7 (N.D. Ill. Sept. 26, 2003). In Robsy, the district court stated, "[t]o determine whether [the disclosure-dedication rule] applies, one must determine when to apply the principle 'deliberately left unclaimed.'" 2003 WL 22232802 at \*7. The district court held that the rule did not apply because the patentee's rejected claims "tried to claim" the subject matter. Id. Janssen, relying heavily on Rosby, also believed that the patentee's application showed the subject matter was not "deliberately left unclaimed." 2014 U.S. Dist. LEXIS 155248 at \*70-73. In short, both courts believed that the patentee's intentions were relevant to the applicability of the disclosure-dedication rule.

But as noted above, *Toro*—a case the Federal Circuit decided in 2004, one year after *Rosby*—dispelled the notion that "deliberately left unclaimed" created an intent requirement. Like Cephalon here and the patentees in *Rosby* and *Janssen*, Toro argued that the disclosure-dedication rule does not apply if the patentee "trie[s] to claim" and "d[oes] not deliberately leave disclosed subject matter unclaimed." *Toro*, 383 F.3d at 1332. The Federal Circuit unquestionably rejected this argument (*id.* at 1333), and therefore, Cephalon's argument has no merit.

Cephalon is wrong when it states that *Johnson & Johnston* "made it clear that a dedication does not occur where, as here the patentee originally sought to claim or did in fact claim the subject matter elsewhere." *See* D.I. 108 at p.9. As explained above,

Johnson & Johnston and its progeny hold that a patent application's claims or a continuation patent's claims do not preclude application of the disclosure-dedication rule to the patent-at-issue. See Zircon Corp. v. Stanley Black & Decker, Inc., 452 F. App'x 966, 978 (Fed. Cir. 2011) (applying the disclosure dedication rule even though the patentee narrowed its independent claims during prosecution to exclude the dedicated matter); Aventis Pharm., Inc. v. Barr Labs., Inc., 335 F. Supp. 2d 558, 570-71 (D.N.J. 2004)(finding the disclosure-dedication rule applied even when the patentee cancelled claims for the alternative subject matter); and CSP Technologies, Inc. v. Sud-Chemie AG, No. 4:11-CV-00029-RLY, 2014 WL 496828, at \*7 (S.D. Ind. Feb. 6, 2014) (applying the disclosure-dedication rule, in part, because a continuation patent claimed the subject matter that the patentee was attempting to recapture with the doctrine of equivalents).

Because the '190 and '863 patent specifications specifically disclose various alternative solvents, but claim only tertiary-butyl alcohol, the disclosure-dedication rule bars Cephalon's claims for infringement against Sagent, DRL, Pharmascience and Innopharma under the doctrine of equivalents as a matter of law.

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